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| 10/532,727      | 04/27/2005  | Yoshikazu Ogura      | 271496US0PCT        | 8749             |

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| EXAMINER |
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WEIER, ANTHONY J

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| ART UNIT | PAPER NUMBER |
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1794

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12/22/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/532,727 | <b>Applicant(s)</b><br>OGURA ET AL. |  |
|                              | <b>Examiner</b><br>Anthony Weier     | <b>Art Unit</b><br>1794             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 11-14, 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 15-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of Group I (claims 1-10 and 15-19) in the reply filed on 7/18/08 is acknowledged.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> Paragraph***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1-4, it is not clear as to what the ratio range of 8/2 to 6/4 is based on. In particular, it is not clear as claimed whether the ratio refers to the catechin composition to solution or the organic solvent to water. Although the Specification sets forth that the ratios refer to the solvent and water mixture, the claims standing alone, as presently written, do not make this clear.

Claims 7-9 are indefinite with respect to the nexus of the recited method claims with those of the independent claims same depend from. Though Applicant argues that claims 7-9 all refer to the starting material of claims 1-4, this is not clearly set forth in the claims. The process of claims 1-4 could actually also refer to the treatment of the caffeine-containing catechin composition in solution (e.g. lines 3 and 4 of claim 1). Furthermore, it is not clear if the solvent and water ratios of claims 7-9 are intended as a narrowing of the solvent and water treatment ratios of claims 1-4 or where these are additional steps used in preparing the caffeine-containing

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catechin composition initially used in independent claims 1-4. Also, in claims 7-9, it is not clear if the range of ratios “10/0 to 8/2” is based on the catechin composition to solution or the organic solvent to water. If it is set forth that the solvent/water treatment of claims 7-9 are intended to further limit the solvent/water ratio of claims 1-4, then the endpoint ratio of 10/0 in claims 7-9 means an embodiment wherein water is not included and this contradicts the use of **both** organic solvent and water as set forth in instant claims 1-4.

### ***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-10 and 15-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-19 and 22-25 of copending Application No. 10/581200. Although the conflicting claims are not identical, they are not patentably distinct from each other because, for example, same vary slightly in the amount of caffeine containing catechin composition (e.g. green tea extract) per mixed solution or

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mixture as well as a difference in range (though overlapping) of the amount of non-polymer catechins contained in said composition. However, such differences are not seen as providing a patentable distinction, and it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the ratios of 10/581200 slightly as a matter of preference depending on, for example, the amount of each component readily available. In addition, the instant claims further recite steps of removing impurities (undissolved solids) and the solvent used. However, it would have been obvious to have included such step in the process claims of 10/581200 since providing same would provide better isolation of or purification of the catechin composition for subsequent consumer use. Otherwise, the instant claims essentially are generic to those of copending Application no. 10/581200. In particular, the claims of 10/581200 recite a process of removing caffeine using a particular ratio of green tea extract containing caffeine with a mixture of organic solvent, water, activated carbon and acid clay or activated clay. The instant claims are generic to same as they provide for treatment of any caffeine containing catechin source.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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6. Claims 1, 3, 5, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 6-128168.

JP 6-128168 discloses a process wherein a caffeine-containing catechin composition (e.g. tea) is treated in a mixture of water and organic acids (e.g. ethanol) in a ratio within the range as set forth in the instant claims (e.g. 100 g tea/ 300 g solution<sup>1</sup>) wherein same is then treated with activated charcoal (i.e. activated carbon) or acid clay, same inherently selectively removing caffeine. See Abstract.

Due to the similarity in processing, it is considered inherent that the extract attained would have a non-polymer catechin to caffeine ratio as called for in instant claim 10.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 3, 5-9, and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 46-39058 taken together with Hara.

JP 46-39058 discloses a process wherein a caffeine-containing catechin composition (e.g. tea) is treated in a mixture of water and organic acids (e.g. ethanol) wherein same is then treated with activated charcoal (i.e. activated carbon) same inherently selectively removing caffeine. JP 46-39058 further discloses the steps of distilling of the solvent as well as further purifying the treated composition (inherently including removal of undissolved solids). See Abstract.

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<sup>1</sup> As set forth in the rejection under 35 USC 112, said claim is broad or indefinite enough to include the

The claims further call for the particular percentage of caffeine-containing catechin composition in said solution or the percentage of organic solvent to water (see rejection under 35 USC 112, 2<sup>nd</sup> paragraph above). Regarding the latter, JP 46-39058 does not appear to disclose the specific organic solvent to water used. However, it is well known in the art to use a solvent solution of between 40 and 75% ethanol (which falls within the range claimed) to effectively extract catechins from tea extracts as taught, for example by Hara et al (col. 2). It would have been obvious to one having ordinary skill in the art at the time of the invention to have employed such water to solvent ratio to effectively extract catechins from the extract of JP 46-39058. It is noted that the instant invention calls for removing caffeine from catechin compositions (e.g. tea). However, the steps employed in JP 46-39058 (along with the solvent ratio of suggested by Hara) are essentially those employed in the instant invention. Therefore, it is inherent that caffeine would be effectively removed from the tea extract as well.

Due to the similarity in processing, it is considered inherent that the extract attained would have a non-polymer catechin to caffeine ratio as called for in instant claim 10 and the particular product limitations as set forth in claim 18.

The claims further call for the non-polymer catechin content of the caffeine-containing catechin composition. Absent a showing of unexpected results, the determination of the most effective particular solids content and/or catechin content of the tea source would have been further obvious through routine experimental optimization.

9. Claims 2 and 4-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 46-39058 taken together with Hara and JP 6-128168.

The claims further call for the use of acid clay in combination with activated carbon. As both are known for removal of impurities from tea extracts as taught, for example, by JP 6-128168, it would have been obvious to one having ordinary skill in the art at the time of the invention to have employed both singly or in combination to provide the same benefit. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. In re Kerkhoven, 205 USPQ 1069.

10. Claims 1-6, 10, and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 6-128168 taken together with Hara.

The claims further call for the use of acid clay in combination with activated carbon. As both are known for removal of impurities from tea extracts as disclosed in JP 6-128168, it would have been obvious to one having ordinary skill in the art at the time of the invention to have employed both singly or in combination to provide the same benefit. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. In re Kerkhoven, 205 USPQ 1069.

The claims further call for the particular percentage of caffeine-containing catechin composition in said solution or the percentage of organic solvent to water (see rejection under 35 USC 112, 2<sup>nd</sup> paragraph above). Regarding the latter, JP 6-128168 does not appear to disclose the specific organic solvent to water used. However, it is well known in the art to use a solvent solution of between 40 and 75% ethanol (which falls within the range claimed) to effectively extract catechins from tea extracts as taught, for example by Hara et al (col. 2). It would have



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been obvious to one having ordinary skill in the art at the time of the invention to have employed such water to solvent ratio to effectively extract catechins from the extract of JP 6-128168. It is noted that the instant invention calls for removing caffeine from catechin compositions (e.g. tea). However, the steps employed in JP 6-128168 (along with the solvent ratio of Hara et al) are essentially those employed in the instant invention. Therefore, it is inherent that caffeine would be effectively removed from the tea extract as well.

Due to the similarity in processing, it is considered inherent that the extract attained would have a non-polymer catechin to caffeine ratio as called for in instant claim 10 and the particular product limitations as set forth in claim 18.

The claims further call for the non-polymer catechin content of the caffeine-containing catechin composition. Absent a showing of unexpected results, the determination of the most effective particular solids content and/or catechin content of the tea source would have been further obvious through routine experimental optimization.

### ***Response to Arguments***

11. Applicant's arguments filed 10/14/09 have been fully considered but they are not persuasive with regard to the prior art rejections. Applicant's arguments regarding the rejection under 35 USC 112, 2<sup>nd</sup> paragraph are addressed in the revision of this rejection above.

Applicant argues that JP '168 does not disclose treatment of tea extract in a solution of 8:2 to 6:4 organic solvent and water. It should be noted, however, that such limitation is not clear in the claims and a rejection under 35 USC 112 above addresses same. That said, JP '168 teaches a caffeine containing catechin composition in a mixed solution at a ratio of 100 g tea/300g solution which falls within the claimed range.

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Applicant further argues that JP '058 and JP '168 fail to disclose the removal of caffeine as claimed. However, this would inherently occur as both JP '058 and JP '168 (using the solvent ratio of Hara) treat a mixture of tea extract, water, and alcohol with activated carbon agent as employed in the instant claims. Even though the references may fail to evince an appreciation of the problem identified and solved by Applicant, same standing alone is not conclusive evidence of the nonobviousness of the claimed subject matter. In other words, the references may suggest doing what Applicant has done even though workers in the art were ignorant of the existence of the problem. In re Gershon et al, 152 USPQ 602.

The Fukuda Declaration submitted 10/14/09 has been considered. However, same does not appear to be commensurate with respect to the range of ethanol and water as set forth in the instant claims (8/2 to 6/4). Moreover, there does not appear to be evidence to show unexpected results using this specific range contrary to ethanol and water ratios just outside those claimed.

All other arguments have been addressed in view of the rejection above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anthony Weier whose telephone number is 571-272-1409. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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December 16, 2009